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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,981	08/07/2001	John W. Shultz	PRO-107.2 6868-82379	5131

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT PAPER NUMBER

1634

DATE MAILED: 11/26/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/924,981

Applicant(s)  
Shultz

Examiner  
Arun Chakrabarti

Art Unit  
1634



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 8/7/01 and 8/7/02
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above, claim(s) is/are withdrawn from consideration.
- 5) ☐ Claim(s) is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) is/are objected to.
- 8) ☐ Claims are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. .  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). .
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8 6) ☐ Other:

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## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

2. Claims 1-23, and 26-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-152 of U.S. Patent No. 6,235,480 B1 in view of Nelson (U.S. Patent 5,401,837) (March 28, 1995).

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Claims 1-152 of U.S. Patent No. 6,235,480 B1 teach the basic and fundamental method of the instant claims 1-16, 19-23, and 26-28, which is the determining the presence or absence of a nucleic acid hybrid in a sample comprising the steps:

a) providing a reaction mixture comprising (I) a sample that may contain a nucleic acid hybrid that comprises a 3'-terminus, (ii) pyrophosphate, (iii) an enzyme that catalyzes the release of a nucleotide from a nucleic acid hybrid, by pyrophosphorolysis of the 3'-terminus of a strand of the nucleic acid hybrid in the presence of pyrophosphate, and

b) maintaining the reaction mixture for a time period and under conditions that permit pyrophosphorolysis of the 3'-terminus of a strand of a nucleic acid hybrid to produce a released nucleotide and a modified 3'-terminus; and

c) assaying the treated sample thereby determining the presence or absence of a nucleic acid hybrid in a sample.

Claims 1-152 of U.S. Patent No. 6,235,480 B1 do not teach the incorporation of a suitable nucleotide into the 3'-terminus of the nucleic acid hybrid to produce an incorporated modified 3'-terminus and assaying the treated sample to determine whether incorporation of the suitable nucleotide into the hybrid occurred.

Nelson teaches the incorporation of a suitable nucleotide into the 3'-terminus of the nucleic acid hybrid to produce an incorporated modified 3'-terminus and assaying the treated sample to determine whether incorporation of the suitable nucleotide into the hybrid occurred (Column 4, line 6 to Column 5, line Column 6, line 28, and Example 1 and Figure 1).

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Claims 1-152 of U.S. Patent No. 6,235,480 B1 do not teach the detection of targets that differ from one another by a single base at an interrogation position.

Nelson teaches the detection of targets that differ from one another by a single base at an interrogation position (Column 4, lines 22-26).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method of the incorporation of a suitable nucleotide into the 3'-terminus of the nucleic acid hybrid to produce an incorporated modified 3'-terminus and assaying the treated sample to determine whether incorporation of the suitable nucleotide into the hybrid occurred of Nelson in the method of claims 1-152 of U.S. Patent No. 6,235,480 B1, since Nelson states, "Exemplified herein is the detection of a single base substitution of the human H-ras protooncogene employing either functionality. The invention technique thus expands the potential application for oligonucleotides as hybridization probes (Column 4, lines 22-26)". An ordinary practitioner would have been motivated to combine and substitute the method of the incorporation of a suitable nucleotide into the 3'-terminus of the nucleic acid hybrid to produce an incorporated modified 3'-terminus and assaying the treated sample to determine whether incorporation of the suitable nucleotide into the hybrid occurred of Nelson in the method of claims 1-152 of U.S. Patent No. 6,235,480 B1 in order to achieve the express advantages, noted by Nelson, of a method that provides detection of a single base substitution of the human H-ras protooncogene employing either functionality, thus expanding the potential application for oligonucleotides as hybridization probes.

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3. Claims 24, and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-152 of U.S. Patent No. 6,235,480 B1 in view of Nelson (U.S. Patent 5,401,837) (March 28, 1995) further in view of Acton et al. (U.S. Patent 6,194,556 B1) (February 27, 2001).

Claims 1-152 of U.S. Patent No. 6,235,480 B1 in view of Nelson teach the method of instant claims 1-23, and 26-28 as described above.

Claims 1-152 of U.S. Patent No. 6,235,480 B1 in view of Nelson do not teach the method, wherein the nucleic acid hybrid is affixed through the attachment of a strand of the nucleic acid hybrid to a solid support.

Acton et al. teach the method, wherein the nucleic acid hybrid is affixed through the attachment of a strand of the nucleic acid hybrid to a solid support (Column 46, lines 33-52).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method, wherein the nucleic acid hybrid is affixed through the attachment of a strand of the nucleic acid hybrid to a solid support of Acton et al. in the method of claims 1-152 of U.S. Patent No. 6,235,480 B1 in view of Nelson, since Acton et al. states, "Accordingly, the identity of numerous allelic variants of one or more genes can be identified in a simple hybridization experiment (Column 46, lines 50-52)". An ordinary practitioner would have been motivated to combine and substitute the method, wherein the nucleic acid hybrid is affixed through the attachment of a strand of the nucleic acid hybrid to a solid support of Acton et al. in the method of claims 1-152 of U.S. Patent No. 6,235,480 B1 in

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view of Nelson in order to achieve the express advantages, noted by Acton et al., of a method that provides identification of numerous allelic variants of one or more genes in a simple hybridization experiment.

***Conclusion***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

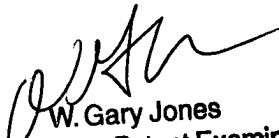
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 746-4979.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

September 17, 2002

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600